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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,475

04/15/2005

Dirk Inze

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

03/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,475	INZE ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,10,12-16,40,43,44 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,10,12-16,40,43,44 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed December 23, 2008 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 28, 2008 has been entered.

Claims 2-3, 5-9, 11, 17-39, 41-42 and 45, are cancelled.

Claims 1, 4, 12, 16, 40, 43, 46 and 50 are currently amended.

Claims 1, 4, 10, 12-16, 40, 43-44 and 46-50 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 10, 13, 40, 43-44 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to a method comprising introducing and expressing in a plant a nucleic acid which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836, and/or modifying level and/or activity of a protein encoded by said nucleic acid, and wherein said yield and/or biomass are increased-relative to corresponding wild type plants, including a method wherein said increased yield and/or biomass comprises increased seed yield, and including a method comprising overexpression of said nucleic acid. These claims are also drawn to a transgenic plant obtainable by said method.

Claims 12, 14-16, 46 and 48-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants and plant cells transgenic for nucleic acid sequences encoding *Arabidopsis* E2Fa and DPa transcription factors, does not reasonably provide enablement for plants and plant cells in which the expression of a nucleic acid which is at least 95% identical to SEQ ID NO:1835 or at least 95% identical to a sequence encoding SEQ ID NO:1836 is otherwise modified, or for plants and plant cells in which the level and/or activity of a protein encoded by said nucleic acid is modified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

These claims are drawn to a transgenic plant or plant cell having increased yield and/or biomass characterized in that said plant has modified expression of a nucleic acid which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a

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sequence encoding SEQ ID NO:1836, and/or modified level and/or activity of a protein encoded by said nucleic acid, and to an ancestor, progeny, or any plant part, particularly a harvestable part, of said transgenic plant. These claims are also drawn to a transgenic plant comprising an isolated nucleic acid sequence which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836.

The specification discloses that the expression of the *Arabidopsis* gene corresponding to SEQ ID NO:1835 (encodes SEQ ID NO:1836) is 1.3 fold or more upregulated in *Arabidopsis* plants and plant cells transgenic for nucleic acid sequences encoding *Arabidopsis* E2Fa and DPa transcription factors (Table 4 page 102).

The specification does not disclose plants or plant cells transformed with SEQ ID NO:1835, or with nucleic acids encoding SEQ ID NO:1836, or with nucleic acids which are at least 95% identical thereto.

The specification also does not disclose other methods or techniques that can be used to specifically modify the expression of SEQ ID NO:1835 or sequences 95% identical thereto.

The specification additionally does not disclose any methods or techniques that can be used to specifically modify the level or activity of SEQ ID NO:1836 or sequences 95% identical thereto.

The invention claimed in claims 1, 4, 10, 13, 40, 43-44 and 47 is not enabled, and the full scope of the invention claimed in claims 12, 14-16, 46 and 48-50 is not enabled, because plants transgenic for a sequence that is natively expressed are not always predictably obtainable, since native and recombinant expression conditions may not be

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equivalent, and because plants having modified levels or activities of a protein are not always predictably obtainable, since conditions that modify gene expression do not always modify the level or activity of the protein encoded by the gene.

See, for example, Sakamoto H. et al. (*Arabidopsis* Cys2/His2-type zinc-finger proteins function as transcription repressors under drought, cold, and high-salinity stress conditions. *Plant Physiol.* 2004 Sep;136(1):2734-46. Epub 2004 Aug 27), who teach that while the native expression of *AZF2* (SEQ ID NO:1835) could be induced by various stresses (page 2740 Figure 5), *Arabidopsis* plants that are transgenic for the *AZF2* coding sequence under the control of the CaMV 35S promoter and that overexpress *AZF2* could not be obtained (page 2741 column 1 first paragraph).

See also, for example, Temple S.J. et al. (Down-regulation of specific members of the glutamine synthetase gene family in alfalfa by antisense RNA technology. *Plant Mol Biol.* 1998 Jun;37(3):535-47), who introduced into alfalfa antisense gene constructs aimed specifically at two distinct classes of Glutamine synthetase 1 genes. While the gene constructs were effective in lowering the corresponding transcript levels, transgenic alfalfa with up to 80% reduction in the transcript level corresponding to the two genes showed no reduction in Glutamine synthetase activity, or in Glutamine synthetase 1 polypeptide level, suggesting that Glutamine synthetase 1 mRNA levels are not rate-limiting for Glutamine synthetase 1 polypeptide synthesis, and that Glutamine synthetase 1 levels are controlled both at the transcriptional and translational/post-translational level. (abstract ; Figures 3, 5 and 6 ; page 541 column 2 and pages 543-545).

In the instant case the specification does not provide sufficient guidance with respect to how to specifically modify the expression of SEQ ID NO:1835 or sequences

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95% identical thereto, other than by transforming *Arabidopsis* plants with nucleic acid sequences encoding *Arabidopsis* E2Fa and DPa transcription factors. In the instant case the specification also does not provide sufficient guidance with respect to how to specifically modify the level or activity of SEQ ID NO:1836 or sequences 95% identical thereto. Absent the requisite guidance, one skilled in the art would have to resort to trial and error experimentation in order to determine by what other manner, if any, the expression of SEQ ID NO:1835 or sequences 95% identical thereto may be modified. Absent the requisite guidance, one skilled in the art would also have to resort to trial and error experimentation in order to determine by what manner, if any, the level or activity of SEQ ID NO:1836 or sequences 95% identical thereto may be modified. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 49 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 15 and 49 are drawn to an ancestor, progeny or plant part of a transgenic plant of claim 12 or claim 46, but are not limited to ancestors, progeny or plant parts that comprise the genetic construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a construct introduced into the parent plant would only

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be transferred to half of the seeds of that plant. In addition, given that there is no indication that there are any other distinguishable characteristics of the claimed ancestors, progeny or plant parts, the claimed ancestors, progeny or plant parts are not distinguishable from those that occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to indicate that the ancestors, progeny or plant parts comprise the genetic construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12, 14-16, 46 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by De Veylder L. et al. (Control of proliferation, endoreduplication and differentiation by the *Arabidopsis* E2Fa-DPa transcription factor. EMBO J. 2002 Mar 15;21(6):1360-8).

The claims are drawn to a transgenic plant or plant cell having increased yield and/or biomass characterized in that said plant has modified expression of a nucleic acid which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836, and/or modified level and/or activity

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of a protein encoded by said nucleic acid, and to an ancestor, progeny, or any plant part, particularly a harvestable part, of said transgenic plant.

The claims are also drawn to a transgenic plant comprising an isolated nucleic acid sequence which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836.

De Veylder L. et al. teach *Arabidopsis* plants and plant cells transgenic for nucleic acid sequences encoding *Arabidopsis* E2Fa and DPa transcription factors (Figure 3).

The transgenic plants have increased yield and/or biomass because these plants contain many more cells, have a greater root diameter, and have cells that comprise more nuclear DNA than nontransformed control plants (page 1365 Figure 6 and Figure 7).

The transgenic plants inherently have modified expression of a nucleic acid which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836, because SEQ ID NO:1835 (encodes SEQ ID NO:1836) is overexpressed in these transgenic plants (Applicant's specification Table 4 page 102)

The transgenic plants inherently comprise plant parts, for example leaves (Figure 3).

The transgenic plants inherently comprise an nucleic acid sequence which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836, because the transgenic plants are *Arabidopsis thaliana* plants, and SEQ ID NOs:1835 and SEQ ID NO:1836 are obtained from *Arabidopsis thaliana* (sequence listing). The endogenous *Arabidopsis thaliana* nucleotide and amino acid sequences are the same whether they have been isolated or not.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC